

OraQuick® Rapid HIV-1 Antibody Test Executive Summary

Product Description:

The OraQuick® Rapid HIV-1 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in fingerstick whole blood specimens. The OraQuick® Rapid HIV-1 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

Price:

\$12.00 U.S. This introductory price is valid through February 28, 2003, after which the price per kit goes to our list price of \$20.00. Shipping is paid by the customer and disclosed once a ship to address and zip code are provided.

Tax Identification Number:

36-4370966

National Stock Number:

100 test kit is: 6550-01-502-6235 25 test kit is: 6550-01-502-6241

Material Provided:

The OraQuick® Rapid HIV-1 Antibody Test, 25 count, test kit - includes 25 devices, 30 loops, 6 test stands, 1 product instruction, 25 subject information pamphlets, and 1 customer letter. The dimensions and weight are (25 Count Box) 12 x 9 x 6 and 2 lbs, respectively.

Materials Required and Available As An Accessory To The Kit:

OraQuick® Rapid HIV-1 Antibody Test Kit Controls. Test Kit Controls contain Positive Control (1 vial, black cap, 0.2 mL) and Negative Control (1 vial, white cap, 0.2 mL), and a Package Insert

Material Required, but not provided:

Timer or watch
Antiseptic wipe
Sterile lancet
Sterile gauze pads
Disposable gloves
Biohazard disposal container

Storage:

Store unused OraQuick® Rapid HIV-1 Antibody Tests unopened at 2°–27°C (35–80°F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to ambient temperature (15°–27°C) before opening.

Shelf Life:

7 months